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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/12/156 03/02/00 TABLET

R 235.00220101

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HM22/0815

EXAMINER

ART UNIT	PAPER NUMBER
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1645

DATE MAILED:

08/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/518,156

Applicant(s)

TARLETON ET AL.

Examiner

Ilesha P Fields

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 40-44, 46-50, 65-67 and 69 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Applicant's election with traverse of Group IV (Paper Number 7) received on July 30, 2001 is acknowledged. Applicant's have elected claims 40-69, *Trypanosoma* as the protozoan species, a polynucleotide as the vaccine component species, and therapeutic immunization as the vaccine administration species. The traversal is on the grounds that the species of Group IV can be searched without serious burden to the Examiner. The argument that the restriction is improper because all of the species found in Group IV can be searched without serious burden is not found persuasive. It is the Examiner's position that it would be an undue burden to search each species found in Group IV. For example prior art of *Trypanosoma* species in claim 41 would not necessarily reveal prior art of *Leishmania*, *Toxoplasma*, or *Eimeria* species recited in the same claim or as the applicant has indicated, a therapeutic immunization could be readily be searched separately from a prophylactic administration. The species recited in the claims are not co-extensive particularly with regard to the literature search thereby necessitating separate searches as indicated by the divergent subject matter and different classification. Consequently, the claims readable on the elected species are claims 40-44, 46-50, 65-67 and 69. Claims 1-39, 45, 51-64, 68, and 70-73 have been withdrawn from further consideration.

The requirement is still deemed proper and is therefore made **FINAL**.

Information Disclosure Statement

The information disclosure statement filed October 4, 2000 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 40-44, 46-50, 65-67 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. in view of Denkers et al.

The claims are drawn to a protozoan vaccine that stimulates a CD8⁺ T cell response.

Lambert et al. (US Patent 5,646,114) disclose a method of therapeutic immunization of a mammal harboring a protozoan infection comprising administering a vaccine. Lambert et al. further disclose that the protozoan species is *Trypanosoma cruzi* (See Detailed Description of the Invention).

Lambert et al. does not teach of a protozoan vaccine that stimulates a CD8⁺ T cell response.

Denkers et al. (Clin. Microbiol. Rev. 1998 Vol. 11 p.569-588) teach that one of the most distinctive features of *Trypanosoma* infection is the strong cell-mediated response (See Entire Document especially page 578 Cytolytic T-Cell Activity Section). Denkers et al. further teach that cytokines such as CD8⁺ contribute greatly to protection of an animal against *Trypanosoma* infection.

Given that 1) Lambert et al. has taught of a method of immunizing a mammal harboring a protozoan infection comprising administering a vaccine and that 2) Denkers et al. has taught that *Trypanosoma* infection elicits a strong cell-mediated response it

would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make a protozoan vaccine that stimulates a CD8⁺ T cell response. One would have been motivated to make such a vaccine in view of the teachings of Denker et al. that identification and cloning of parasite molecules could lead to the development of new vaccines.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Iesha Fields

August 13, 2001



MARK NAVARRO
PRIMARY EXAMINER